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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,480

11/15/2005

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20747/210

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12/01/2009

EXAMINER

SZNAIDMAN, MARCOS L

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

12/01/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/511,480	<b>Applicant(s)</b> JABBOUR ET AL.	
	<b>Examiner</b> MARCOS SZNAIDMAN	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,9,12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,9,12 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This is office action is in response to applicant's request for continued examination filed on September 28, 2009.

Receipt of Declarations under 37 CFR 1.132 is acknowledged.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

#### ***Status of claims***

Amendment of claims 1 and 3-5 and cancellation of claim 32 is acknowledged.

Claims 1, 3-5, 9, and 12-13 are currently pending and are the subject of this office action.

Claims 1, 3-5, 9, and 12-13 are presently under examination.

#### ***Priority***

The present application is a 371 of PCT/GB03/01521 filed on 04/10/2003, which claims priority to foreign application: United Kingdom 0208785.6 filed on 04/17/2002.

***Rejections and/or Objections and Response to Arguments***

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 112 (Maintained Rejection)***

Claims 1, 3-5, 9, 12-13 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The reasons for this rejection have been provided in the previous office action dated April 28, 2009 and in the advisory action dated 08/31/09, the text of which are incorporated by reference herein.

Applicant's arguments have been fully considered but are not persuasive.

Applicant arguments are very similar to the ones previously presented: in the 1.132 declaration and in its remarks, Applicant argues that the specification provides enough data to overcome the enablement rejection. Applicant insists in presenting more mechanistic arguments related to the role that FP receptor expression plays in pathological conditions of the uterus such as uterine cancer, fibroids and endometriosis.

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Accordingly one of skill in the art would have no reason to doubt that FP receptor antagonism would be useful in treating uterine cancer, fibroids and endometriosis as recited in amended claim 1.

Examiner's response: although there is no denial that FP receptor expression plays a role in some pathological condition of the uterus, this is not the same to say that an FP receptor antagonist will be effective in treating those conditions. As mentioned in previous office actions, and without judging the scientific relevance of the data presented, Applicant has not provided enough experimental data that will correlate antagonizing the FP receptor and the treatment of any disease of the uterus. Regardless of how strong the mechanistic data points into the role of FP receptors in conditions of the uterus, the fact is that in a such unpredictable art as in the treatment of cancer, Applicant has not provided the minimum required data for enablement:: *in vitro* or *in vivo* data showing that an FP receptor antagonist can inhibit cancer cell growth *in vitro* and/or decrease tumor growth *in vivo*. The prior art is full of examples with strong scientific and mechanistic rationale that have failed or came short of the predictions.

Applicant has not provided any correlation between antagonizing the FP receptor and the treatment of any disease of the uterus, except for some scientific speculation. As such the examples presented by Applicant do not constitute working examples. While it is understood that the absence of working examples should never be the sole reason for rejecting a claims as being broader than an enabling disclosure, the criticality of working examples in an unpredictable art, such as the treatment of diseases of the uterus, is required for practice of the claimed invention.

In summary, the scientific rationale provided by Applicant has to be supported with *in vitro* and/or *in vivo* data in order to overcome the enablement rejection.

Applicant argues: The PTO asserts that "[a]pplicant did not provide a single cell assay that shows that any FP receptor antagonist could prevent or ameliorate the proliferation of a cancerigenous [sic] cell" (office action at page 6). However, as acknowledged by the PTO, "[c]ancer is a very complex disease that involves several mechanisms". Accordingly, direct prevention of the proliferation of cancerous cells is not a requirement of an anti-cancer agent.

Examiner's response: it is not clear why Applicant arrived at the above conclusion, however, and contrary to Applicant's conclusion, a decrease in the proliferation of cancerous cells is direct proof of the efficacy of an anti-cancer agent and it is precisely the type of data that Applicant needs to present in order to overcome the enablement rejection

### ***Conclusion***

No claims are allowed.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/  
Examiner, Art Unit 1612  
November 17, 2009

/Gollamudi S. Kishore/  
Primary Examiner, AU 1612